

REMARKS

Applicants note that all amendments, cancellations, and additions of Claims presented herein are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),¹ and without waiving the right to prosecute the cancelled claims (or similar claims) in the future.

In the Final Office Action mailed 10/17/08, the Examiner objected to the Declaration of inventor Evan Singer because the date was not included. The Applicants provide a replacement declaration herewith.

In the Final Office Action mailed 10/17/08, the Examiner objected to Claim 11 as being in improper dependent form for depending on a canceled claim. The Applicants have amended Claim 11 to depend on Claim 1. As such, the Applicants respectfully request that the objection be withdrawn.

In the Final Office Action mailed 10/17/08, the Examiner issued several rejections. Each of the rejections is discussed in detail below.

I. The Claims are Non-Obvious

In the Final Office Action mailed 10/17/08, the Examiner issued several rejections under 35 U.S.C. 103. Each of the rejections is discussed in detail below.

A. The Claims are Not Obvious in Light of Sanga in View of Titmas

The Examiner rejects Claims 1, 3-5, 8, 10 and 11 under 35 U.S.C. 103(a) as allegedly being obvious in light of Sangha (US 5,334,502; hereinafter Sangha) as evidence by Levitskii et al (Ukrainskii Biokimicheskii Zhurnal, 1979, 51:3, p. 289; English abstract only; hereinafter Levitski) in view of Titmas (US 5,334,502; hereinafter Titmas). The Applicants respectfully disagree. Nonetheless, in order to further the business interests of the Applicants, and without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG), and without waiving the right to prosecute the cancelled claims (or similar claims)

¹ 65 Fed. Reg. 54603 (Sept., 8, 2000).

in the future, the Applicants have amended Claim 1 to recite that the reaction site further comprises an alcohol oxidase enzyme and a peroxidase enzyme.

The Examiner states "Although Sangha disclose the measurement of the peroxidase enzyme found in saliva they are silent with respect to the use of potassium iodide. However, this deemed inherent to the teachings of Sangha because potassium iodide is a known substrate for peroxidase activity in saliva." As noted in their previous response to office action, the Applicants respectfully disagree and submit that the Examiner has improperly applied rejection by inherency. As stated in M.P.E.P. 2112:

"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) and

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)

The Examiner has provided no intrinsic or extrinsic evidence that potassium iodide **is present** in the teachings of Sangha, inherently or otherwise. The fact that it could possibly be present or useful (which the Applicants submit it is not) does not constitute an inherent property or characteristic. The extrinsic evidence provided by the Examiner (Levitski) is directed to an assay for peroxidase in human saliva, not an assay for alcohol in saliva. In addition, unlike the present invention, Sangha is directed to an assay for **peroxidase enzyme** in saliva, not alcohol in saliva. Thus, not only are the teaching of Sangha not relevant to the assay of the presently claimed invention, the Examiner has not provided evidence that the teachings of Sangha include the use of a potassium iodide chromagen for detection of alcohol in saliva, inherently or otherwise. As such, rejection by inherency is not applicable to the presently claimed invention.

Thus, the Applicants submit that the cited references, alone or in combination, do not teach an assay for detection of alcohol in saliva that utilizes a potassium iodide chromagen.

In addition, even if the use of potassium iodide as a chromagen is improperly read into the methods of Sangha as being inherent, the cited references do not provide a motivation to

combine the reference with a reasonable expectation of success². The Federal Circuit has recently addressed this issue of biotechnology inventions in respect to *KSR* in *Eisai Co. Ltd. v. Dr. Reddy's Laboratories, Ltd.*, 533 F.3d 1353, 87 U.S.P.Q.2d 1452 (Fed. Cir. 2008):

The Supreme Court's analysis in *KSR* thus relies on several assumptions about the prior art landscape. First, *KSR* assumes a starting reference point or points in the art, prior to the time of invention, from which a skilled artisan might identify a problem and pursue potential solutions. Second, *KSR* presupposes that the record up to the time of invention would give some reasons, available within the knowledge of one of skill in the art, to make particular modifications to achieve the claimed compound. See *Takeda*, 492 F.3d at 1357 ("Thus, in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound."). Third, the Supreme Court's analysis in *KSR* presumes that the record before the time of invention would supply some reasons for narrowing the prior art universe to a "finite number of identified, predictable solutions," 127 S.Ct. at 1742. In *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, 520 F.3d 1358, 1364 (Fed.Cir.2008), this court further explained that this "easily traversed, small and finite number of alternatives ... might support an inference of obviousness." To the extent an art is unpredictable, as the chemical arts often are, *KSR*'s focus on these "identified, predictable solutions" may present a difficult hurdle because potential solutions are less likely to be genuinely predictable.

For example, as noted above, Sangha is not directed to an assay for detection of alcohol in saliva. Titmas is completely silent as to the use of potassium iodide in alcohol detection assays. Titmas provides a commercial alcohol detection assay and is silent as to the need for additional assays. There is no finite number of solutions that would yield the assay of the presently claimed invention. The use of potassium iodide in the assays of the presently claimed invention is neither suggested by the combination of references cited by the Examiner nor predictable based on the cited references or the knowledge in the art.

² The test for *prima facie* obviousness is consistent with legal principles enunciated in *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007). The Federal Circuit summarized the Supreme Court's holding in *KSR* that "While the *KSR* Court rejected a rigid application of the teaching, suggestion, or motivation ("TSM") test, the Court acknowledged the importance of identifying 'a *reason*' that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does' in an obviousness determination." *Takeda Chem. Indus., Ltd. v. Alphapharma Pty., Ltd.*, 06-1329, slip op. (Fed. Cir. June 28, 2007), at 13-14 (quoting *KSR*, 127 S. Ct. at 1731) (emphasis added). Although the TSM test should not be applied in a rigid manner, it can provide helpful insight to an obviousness inquiry. *KSR*, 127 S. Ct. at 1731. The *KSR* Court upheld the secondary considerations of non-obviousness, noting that there is "no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis." *Id.* Additionally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. See M.P.E.P. 2143.

In addition, the Examiner has provided no evidence that even if the cited references are improperly combined, that a reasonable expectation of success exists, should the combination be carried out. The Patent Office's own "Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc."³ states that a finding of obviousness requires: both "a finding that there had been a finite number of identified, predictable potential solutions to the recognized need or problem..." and "a finding that one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success..." Nothing in any of the cited references teaches or suggests that potassium iodide is capable of acting as a successful chromagen or that potassium iodide: 1) is compatible with in mouth saliva; and 2) produces a visible color change in response to particular alcohol concentrations (but not others) correlated with blood alcohol levels; i.e. the art does not teach or suggest that potassium iodide is a **sufficiently sensitive and robust chromagen** to function as claimed.

Accordingly, the Applicants submit that the Examiner has not demonstrated a prima facie case of obviousness and respectfully request that the rejection be withdrawn.

B. The Claims are Not Obvious in Light of Sangha in view of Titmas and Spring

The Examiner rejects Claim 7 under 35 U.S.C. 103 as allegedly being obvious in light of Sangha as evidenced by Levitski in view of Spring et al. (US 5,643,721; hereinafter Spring). This rejection is moot as Claim 7 has been cancelled.

C. The claims are Not Obvious in Light of Sangha in view of Titmas and Brogema

The Examiner further rejects Claims 6 and 12-15 under 35 U.S.C. 103 as allegedly being obvious in light of Sangha as evidenced by Levitski in view of Titmas and Bogema (US 6,248,598; hereinafter Bogema). The Applicants respectfully disagree and submit that the Examiner has not demonstrated a prima facie case of obviousness because the cited references do not provide a motivation to combine the references with a reasonable expectation of success. Nor do the cited references teach all of the elements of the claims. As described above, Neither Sangha nor Titmas, alone or in combination provide a motivation to combine the cited references with a reasonable expectation of success. Nor do Sangha and Titmas teach the claim element of

³ **Federal Register** / Vol. 72, No. 195 / Wednesday, October 10, 2007

the chromagen being potassium iodide. Bogema neither teaches the use of potassium iodide chromagens nor provides a motivation to combine Sangha and Titmas with a reasonable expectation of success. As such, Examiner has not demonstrated a prima facie case of obviousness under 35 U.S.C. 103 and the rejection should be withdrawn.

CONCLUSION

All grounds of rejection of the Final Office Action mailed 10/17/08 have been addressed and reconsideration of the application is respectfully requested. It is respectfully submitted that Applicants' claims as amended should be passed into allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

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